

Remarks

Claims 104-109 were pending in the subject application. By way of the amendment of this date, claims 108-109 have been canceled. Therefore, claims 104-107 are now before the Examiner for consideration. The subject invention provides unique and advantageous solid supports for the solid phase synthesis of polynucleotides. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

In the Office Action, the Examiner states that some of the schemes found at page 20-22 of the specification are illegible, and requests substitution of clearly drawn schemes. Applicants respectfully submit that substitute pages 20-22 were included with the Amendment, filed February 15, 2001, submitted by previous counsel for Applicants.

The Office Action has rejected claims 104-107 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey, to one skilled in the relevant art, that the inventors were in possession of the invention at the time the application was filed. Specifically, the Office Action argues that the formulas of claims 104-107 show a bond directly between the 2- or 3- carbon of a ribose moiety and the linker moiety "X". The Office Action argues that the reaction schemes, at pages 20-22, suggest that none of the chemical formulas are enabled by exemplifications in the disclosure. While the intent of the rejection is unclear, because it appears to combine the written description and enablement requirements of § 112, first paragraph, Applicants submit that the specification provides both written description and enablement for the instant invention.

As the Examiner is no doubt aware, the written description and enablement requirements are separate and distinct (see, e.g. MPEP § 2161). In the present case the Office Action, at pages 3-4, states that the claims contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention (consistent with a written description rejection), and continues that the specification is non-enabling in that pages 20-22 of the specification suggest that none of the chemical formulas provided within the instant claims is enabled in any way by the exemplifications of the disclosure (suggesting an enablement rejection). The Examiner then directly combines the two requirements in the following sentence, alleging that the disclosure does not "provide an adequately supportive written description which

would permit the ordinary practitioner to practice the synthesis of, or the use of, the materials claimed herein." Regardless of the intended basis of the rejection, Applicants submit that the Examiner has failed to make a proper rejection under § 112, first paragraph. Further, as discussed *infra*, Applicants assert that the present claims meet both the written description and the enablement requirements of § 112, first paragraph.

When rejecting a claim under the enablement requirement of section 112, the examiner bears the "initial burden of setting forth a reasonable explanation as to why [he/she] believes that the scope of protection provided by [the] claim is not adequately enabled by the description of the invention provided in the specification." *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). To object to a specification on the grounds that the disclosure is not enabling with respect to the scope of a claim sought to be patented, the examiner must provide evidence or technical reasoning substantiating those doubts. *Id.*; and MPEP § 2164.04. Without a reason to doubt the truth of the statements made in the patent application, the application must be considered enabling. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). Accordingly, the case law makes clear that properly reasoned and supported statements explaining any failure to comply with Section 112 are a requirement to support a rejection. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

In the case of this rejection, it is respectfully submitted that the Office Action has failed to set forth any objective evidence that establishes that the skilled artisan would be unable to make and/or use the instantly claimed invention. The Office Action has pointed to reaction schemes at pages 20-22 in an effort to support the rejection for lack of enablement; however, these passages are related to exemplary schemes depicting the detritylation and coupling of nucleosides to supports of the instant invention (see page 18, line 22 through page 19, line 18).

Applicants respectfully submit that the specification provides adequate written description of the invention and teaches how to make and use the claimed invention. For example, page 7, line 23 through page 17, line 4 (for example, page 15, line 11 to page 17, line 4) describe the preparation of the compounds, and their use is discussed throughout the specification, e.g., at page 13, line 6 to page 15, line 2). Particularly, the specification, at page

10, lines 2-5, states that a polymer may be directly linked to the present compounds via a hydrocarbon radical linker:

[o]ne of  $R^1$ ,  $R'^1$ ,  $R''^1$ ,  $R^2$  and  $R'^2$  represents an inorganic or organic polymer  $-\textcircled{P}$  or a hydrocarbon radical substituted with an inorganic or organic polymer... (emphasis added)

Further, page 11, lines 4-6 of the specification, states that the structures of the invention may take the form of a ribose:

According to one embodiment variant,  $R^1$  and  $R^2$  or  $R'^1$  and  $R'^2$  together form a ring, in particular a heterocycle, on which the polymer is found substituted.

In particular, it is possible for ( $R^1$  and  $R^2$ ) or ( $R'^1$  and  $R'^2$ ) together to form a ribose and for Nu to represent the 2'O function protected with a protecting group such that Nu represents  $\text{CH}_3\text{-CO}$ , for example. (emphasis added)

Accordingly, it is respectfully submitted that the specification provides written description of linkers and solid supports attached to both the 2- and 3- carbon of the ribose moiety; reconsideration and withdrawal of the rejection is respectfully requested.

Regarding the enablement of the present claims, Applicants assert that the present Office Action fails to provide a proper basis for a rejection of the claims for lack of enablement, and, further, that the present claims were indeed fully enabled at the time of filing. The test for enablement is whether the experimentation needed to make and use the claimed invention is undue or unreasonable. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). In making an enablement rejection under 35 U.S.C. § 112, first paragraph, the examiner bears the initial burden of setting forth a reasonable explanation as to why it is believed that the scope of protection provided by the claims is not adequately enabled by the specification. See, *In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993); MPEP § 2164. Finally "[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." See, MPEP § 2164.02.

In the present case, the Office Action has failed to meet the burden for making an enablement rejection, as no reasoning whatsoever has been provided to support the contention that one of skill in the art would have required undue experimentation in order to make and use the claimed structures. In fact, the only basis that the Office Action makes for this rejection is to say, in reference to the bond between the 2- or 3- carbon of a ribose moiety and the linker attached to the solid support, that the disclosure at pages 20-22 "suggests that none of the formulas provided within the instant claims is enabled in any way by the exemplifications of the disclosure." See, page 3 of the Office Action (underlining in original). It is respectfully submitted that the Office Action applies an improper standard for enablement.

As stated above, enablement rests upon whether one of skill in the art would have been able to make and use the claimed invention at the time of filing without undue experimentation, not whether particular examples are provided in the specification. Further, as noted above, the Examiner has provided no evidence or reasoning indicating that one of skill in the art would not have been capable of making and using the claimed invention without undue experimentation at the time of filing, which is the proper test of enablement. In the absence of such reasoning, this rejection cannot stand and should be withdrawn.

Finally, even if a proper enablement rejection had been made, Applicants note that the specification provides extensive teaching regarding the preparation of the compounds of the invention. For example, page 15, line 11 to page 17, line 4, describe the preparation of the compounds, and their use is discussed throughout the specification, *e.g.*, at page 13, line 6 to page 15, line 2. Accordingly, one of skill in the art would have been able to make and use the invention at the time of filing. In view of the foregoing arguments, Applicants respectfully submit that the present claims are both adequately described and fully enabled by the specification, as filed, and thus the rejection of the claims under 35 U.S.C. § 112, first paragraph, should be withdrawn.

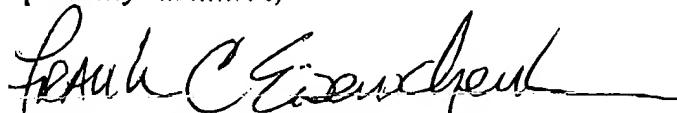
In view of the foregoing remarks and the amendments to the claims, Applicants believe that the pending claims are now in condition for allowance, and such action is respectfully requested. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

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Applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Transmittal Form (in duplicate)  
Fee Transmittal Form (in triplicate)  
Petition for One-Month Extension of Time